FEB 2 8 2005

10. SUMMARY OF 510(k)

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K042272.

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121
Tel.: 858-535-2030
Fax: 858-535-2038

Establishment Registration Number: 2531491
Owner/Operator Number: 9063887

Date:

August 20, 2004

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® *Mononucleosis* Rapid Test Strip (Whole Blood/Serum/Plasma)
ACON® *Mononucleosis* Rapid Test Device (Whole Blood/Serum/Plasma)

Common Name:

Immunochromatographic test for the qualitative detection of heterophile antibodies specific to infectious *Mononucleosis.*

Classification Information:

The ACON® *Mononucleosis* Rapid Test Strip and Test Device (Whole Blood/Serum/Plasma) are similar to other FDA-cleared devices for the qualitative detection of heterophile antibodies specific to infectious *Mononucleosis*.

Classification: Class II

Regulation Number: 866.5640

Product Code: KTN

Classification Name: System, test, Infectious *Mononucleosis*

Complexity: Moderate

Analyte: Heterophile antibodies specific to infectious *Mononucleosis* in human blood, serum or plasma

Test Category: Manual procedures with limited steps and limited sample and reagent preparation

Intended Use:

The ACON® *Mononucleosis* Rapid Test Strip and Test Device (Whole Blood/Serum/Plasma) are rapid chromatographic immunoassays for the qualitative detection of heterophile antibodies to infectious *Mononucleosis* in whole blood, serum or plasma to aid in the diagnosis of infectious *Mononucleosis* infection in adults at 18 years of age and older. They are intended for health professionals including professionals at point-of-care sites.

Description:

The ACON® *Mononucleosis* Rapid Test Strip and the ACON® *Mononucleosis* Rapid Test Device are lateral flow immunochromatographic assays for the qualitative detection of heterophile antibodies associated with infectious *Mononucleosis* in whole blood, serum or plasma. They utilize purified IM heterophilic antigen-coated particles and IM heterophilic antigen-coated on the membrane to selectively detect elevated levels of heterophile antibodies to infectious *Mononucleosis*. These tests can be performed without the use of an instrument.

Comparison to Predicate Devices:

A summary of comparison of the features of the ACON® *Mononucleosis* Rapid Test Strip, the ACON® *Mononucleosis* Rapid Test Device, and the predicate device is shown below:

Table 2. ACON *Mononucleosis* Rapid Tests versus Genzyme OSOM® Mono Test

Feature	ACON® *Mononucleosis* Rapid Test Strip	ACON® *Mononucleosis* Rapid Test Device	Genzyme OSOM® Mono Test
Indication for use	A rapid chromatographic immunoassay for the qualitative detection of heterophile antibodies to infectious *Mononucleosis* in whole blood to aid in the diagnosis of infectious *Mononucleosis* infection.	A rapid chromatographic immunoassay for the qualitative detection of heterophile antibodies to infectious *Mononucleosis* in whole blood to aid in the diagnosis of infectious *Mononucleosis* infection.	A lateral-flow immunoassay intended for the qualitative detection of heterophile antibodies specific to infectious *Mononucleosis* in whole blood to aid in the diagnosis of infectious *Mononucleosis* infection.
Intended Use	Professional	Professional	Professional
Intended specimen	Whole blood, serum, plasma	Whole blood, serum, plasma	Whole blood, serum, plasma
Endpoint	Colored Lines	Colored Lines	Colored Lines
Materials provided	Test strips Disposable sample test tubes Disposable droppers Capillary tube Dispensing bulb Positive control Negative control Buffer Package insert Procedure card	Test devices Disposable droppers Capillary tube Dispensing bulb Positive control Negative control Buffer Package insert Procedure card	Test devices Disposable droppers Capillary tube Positive control Negative control Direction insert Procedure card Package Insert
Methodology	Membrane particle assay	Membrane particle assay	Membrane particle assay
Test Time	5 minutes	5 minutes	5 minutes
Format	Antigen/antibody immunoassay	Antigen/antibody immunoassay	Antigen/antibody immunoassay

Accuracy

A clinical evaluation was conducted using a total of 611 clinical specimens. The detection of infectious *Mononucleosis* specific heterophile antibodies in clinical specimens including the whole blood , serum, and plasma samples was done by using the ACON® *Mononucleosis* Rapid Test Strip and Test Device (Whole Blood/Serum/Plasma) and Predicate Device, Genzyme OSOM® Mono Test.

ACON® *Mononucleosis* Rapid Test Strip compared to Genzyme OSOM® Mono Test - Whole Blood

Positive Agreement = 49/51 = 96% (87%-99%)*
Negative Agreement = 80/80 > 99% (95%-100%)**
Overall Agreement = 129/131 = 98% (95%-99%) *
* 95% Confidence Interval
** Since the portion can not go above 100%, this is really a 97.5% confidence interval.

ACON® *Mononucleosis* Rapid Test Strip compared to Genzyme OSOM® Mono Test - Plasma

Positive Agreement = 59/60 = 98% (91%-99%)*
Negative Agreement = 180/180 > 99% (98%-100%)**
Overall Agreement = 239/240 > 99% (98%-99%)*
* 95% Confidence Interval
** Since the portion can not go above 100%, this is really a 97.5% confidence interval.

ACON® *Mononucleosis* Rapid Test Strip compared to Genzyme OSOM® Mono Test – Serum

Positive Agreement = 73/73 > 99% (95%-100%)**
Negative Agreement = 167/167 > 99% (98%-100%)**
Overall Agreement = 240/240 > 99% (98%-100%)**
** Since the portion can not go above 100%, this is really a 97.5% confidence interval.

ACON® *Mononucleosis* Rapid Test Strip compared to Genzyme OSOM® Mono Test – All Specimens

Positive Agreement = 181/184 = 98% (95%-99%)*
Negative Agreement = 427/427 > 99% (99%-100%)**
Overall Agreement = 608/611 > 99% (99%-99.9%)*
* 95% Confidence Interval
** Since the portion can not go above 100%, this is really a 97.5% confidence interval.

ACON *Mononucleosis* Rapid Device compared to Genzyme OSOM® Mono Test – Whole Blood

Positive Agreement = 50/51 = 99% (90%-99%)*
Negative Agreement = 80/80 > 99% (95%-100%)**
Overall Agreement = 130/131 > 99% (96%-99%)*
* 95% Confidence Interval
** Since the portion can not go above 100%, this is really a 97.5% confidence interval.

ACON *Mononucleosis* Rapid Test Device compared to Genzyme OSOM® Mono Test - Plasma

Positive Agreement = 59/60 = 98% (91%-99%)*
Negative Agreement = 180/180 > 99% (98%-100%)**
Overall Agreement = 239/240 > 99% (98%-99%)*
* 95% Confidence Interval
** Since the portion can not go above 100%, this is really a 97.5% confidence interval.

ACON *Mononucleosis* Rapid Test Device compared to Genzyme OSOM® Mono Test - Serum

Positive Agreement = 72/73 = 99% (93%-99%)*
Negative Agreement = 167/167 > 99% (98%-100%)**
Overall Agreement = 239/240 > 99% (98%-99%)*
* 95% Confidence Interval
** Since the portion can not go above 100%, this is really a 97.5% confidence interval.

ACON *Mononucleosis* Rapid Test Device compared to Genzyme OSOM® Mono Test – All Specimens

Positive Agreement = 181/184 = 98% (95%-99%)*
Negative Agreement = 427/427 > 99% (99%-100%)**
Overall Agreement = 608/611 > 99% (99%-99.9%)*
* 95% Confidence Interval
** Since the portion can not go above 100%, this is really a 97.5% confidence interval.

POL Study Summary:

Utilizing a proficiency panel of coded, blinded and randomized plasma and whole blood specimens, POL studies were conducted on both types of specimens at three distinct sites. POL study results on the plasma specimens indicate that with the exception of two "false negative" results registered by one of the three POL sites, all POL study results were found to be within the expected results (178/180, 98.9%). POL study results on whole blood specimens show an overall 100% agreement (180/180) when compared to the expected results. These POL study results indicate that personnel at different doctors' offices could properly perform the ACON® *Mononucleosis* Rapid Test Strip and Test Device (Whole Blood/Serum/Plasma), as well as interpret the correct test results comparable to those obtained by a trained lab technician (120/120, 100%).

Conclusion:

Clinical and laboratory studies included in this 510(k) submission demonstrate that the ACON *Mononucleosis* Rapid Test Strip and Test Device (Whole Blood/ Serum/ Plasma) are substantially equivalent to the predicate device, Genzyme OSOM® Mono Test, which is already marketed in the U. S. These studies also demonstrate that these ACON *Mononucleosis* Rapid test products are suitable for use by the professionals including professionals at the point-of-care sites.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 8 2005

Edward Tung, Ph.D.
Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd.
San Diego, CA 92121

Re: k042272
Trade/Device Name: ACON Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma)
ACON Mononucleosis Rapid Test Strip (Whole Blood/Serum/Plasma)
Regulation Number: 21 CFR 866.5640
Regulation Name: Infectious Mononucleosis Immunological Test System
Regulatory Class: Class II
Product Code: KTN
Dated: August 20, 2004
Received: August 23, 2004

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Robert L. Becker, Jr., M.D., PhD
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

9. INDICATIONS FOR USE

510(k) Number (if known): K042272

Device Name: ACON® *Mononucleosis* Rapid Test Strip (Whole Blood/Serum/Plasma)
ACON® *Mononucleosis* Rapid Test Device (Whole Blood/Serum/Plasma)

Indications For Use: The ACON® *Mononucleosis* Rapid Test Strip and the ACON® *Mononucleosis* Rapid Test Device are rapid chromatographic immunoassays for the qualitative detection of heterophile antibodies specific to infectious *Mononucleosis* in human whole blood, serum or plasma to aid in the diagnosis of infectious *Mononucleosis* infection in adults at 18 years of age and older. They are intended for healthcare professionals including professionals at point-of-care sites.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K042272